

REMARKS

Status of the Claims

Claims 1-9, 15 and 21-24 are pending in this application. Claims 1 and 2 were amended to expressly recite the point of pegylation and specify that the -NH- moiety of -NH-R is the amine terminal α -amino group of human growth hormone or methionyl human growth hormone. Support for amendment to claims 1 and 2 can be found, for example, in paragraphs [0047],¹ [0060], [0061] and Example 1.

Rejection Under 35 U.S.C. §112, First Paragraph

Reconsideration is respectfully requested of the rejection of claims 1-9, 15 and 21-24 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor(s), at the time the application was filed, had possession of the claimed invention. While it is maintained that claims 1 and 2 satisfied the requirements of 35 U.S.C. 112, first paragraph, as previously presented, they have been amended to amplify the requirement that the hGH is monopegylated and that it is pegylated at the amine terminal α -amino group. As such, a complete conjugated structure is presented in the claims.

Rejection Under 35 U.S.C. §112, Second Paragraph

Reconsideration is respectfully requested of the rejection of claims 1-9, 15 and 21-24 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. While it is maintained that claims 1 and 2 satisfied the requirements of 35 U.S.C. 112, second paragraph, as previously presented, they have been amended to amplify the requirement that the hGH is monopegylated and that it is pegylated at the amine terminal α -amino group. As such, the actual structure is not unclear.

¹ Paragraph numbering is based on the published U.S. application US 2004/0127417, published on July 1, 2004.

Telephone Interview

Applicant's undersigned counsel wishes to acknowledge a telephone interview with Examiner Audet on October 24, 2007. During this conference, the amendments made herein to claims 1 and 2 were proposed and discussed with one exception: during the interview, applicant's counsel did not then propose canceling "at the N-terminus thereof." This further amendment is proposed herein to eliminate any potential redundancy with the phrase "the -NH- moiety of -NH-R is the amine terminal α -amino group" which has been added to the claim. During the telephone interview, the Finn declaration, submitted in August, 2007, was also discussed in connection with the 35 U.S.C. 112, first and second paragraph rejections. In particular, paragraphs 9 and 10 of the Finn declaration were discussed wherein Rory F. Finn acknowledges that the butyraldehyde pegylation reagent he used to pegylate hGH is described in Nektar Therapeutics' U.S. Patent No. 7,157,546. It was understood that the Examiner would consider these amendments, but no agreement as to patentability was reached during the telephone interview.

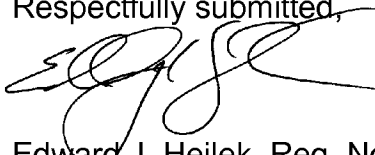
Related Prosecution

Applicant wishes to bring to the Examiner's attention prosecution of a related application, namely U.S. application serial no. 10/771,895, which claims priority as a continuation-in-part of the present application. In U.S. application serial no. 10/771,895, claim 1 was directed to "A method for the treatment of a disease or disorder in which use of growth hormone is beneficial, comprising administering to a patient in need thereof a therapeutically effective amount of a poly(ethylene glycol)-modified hGH having the structure of formula I or II [the same formulae as appeared in claim 1 of the present application]..." This claim was rejected, and the rejection was made final, under 35 U.S.C. 103 in view of two articles, Rockich et al (Research Report presented at the annual meeting of the American Association of Pharmaceutical Scientists, Boston, MA, 1432-436, 1997 and Hitoshi et al., (Brain Injury, Vol. 14, No. 7 669-676, 2000. Neither publication discloses the hGH conjugate claimed herein.

CONCLUSION

In light of the foregoing, Applicant respectfully requests entry of the claim amendments, and solicit an allowance of the claims. In any event, entry of the amendments proposed herein is proper under 37 C.F.R. 1.116 in that the amendments place the claims in better form for consideration on appeal.

The Examiner is invited to contact the undersigned attorney should any issues remain unresolved.

Respectfully submitted,


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